

AUSTRALIA

Patents Act 1990

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## REQUEST FOR A STANDARD PATENT

## AND NOTICE OF ENTITLEMENT

The Applicant identified below requests the grant of a patent to the nominated person identified below for an invention described in the accompanying standard complete patent specification.

[70.71]Applicant and Nominated Person:

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AMERICA

[54]Invention Title:

**COSMETIC COMPOSITIONS HAVING KERATOLYTIC AND ANTI-ACNE  
ACTIVITY**

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[31.33.32]

Details of basic application(s):-

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Applicant states the following:

1. The nominated person is the assignee of the actual inventor(s).

2. The nominated person is

~~- the applicant~~

~~- the assignee of the applicant~~

~~- authorised to make this application by the applicant~~

of the basic application.

3. The basic application(s) was/were the first made in a convention country in respect of the invention.

The nominated person is not an opponent or eligible person described in Section 33-36 of the Act.

21 June 1995

Revlon Consumer Products Corporation  
By PHILLIPS ORMONDE & FITZPATRICK  
Patent Attorneys  
By

Our Ref : 415006

5999q

*David B Fitzpatrick*

MO 69686 210895



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(54) Title  
**COSMETIC COMPOSITIONS HAVING KERATOLYTIC AND ANTI-ACNE ACTIVITY**

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(57) Claim

1. A cosmetically acceptable composition with keratolytic activity comprising:  
0.01 to 25% by weight of a keratolytic compound complexed to a carrier molecule.  
75-99.99% by weight of a diluent.
8. A composition according to any one of the preceding claims wherein the diluent is a make-up containing 5-70% oil, 10-95% water, and 5-40% pigment.
11. A method for treating acne vulgaris comprising:
  - (a) complexing a keratolytic compound to a carrier molecule.
  - (b) adding an effective amount of said complex of (a) to a cosmetically acceptable diluent.
  - (c) applying the composition of (b) to a subject's face at least once per day.

**AUSTRALIA**

Patents Act

**COMPLETE SPECIFICATION  
(ORIGINAL)**

Class                      Int. Class

Application Number:  
Lodged:

Complete Specification Lodged:  
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Related Art:

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Invention Title:

**COSMETIC COMPOSITIONS HAVING KERATOLYTIC AND ANTI-ACNE  
ACTIVITY**

Our Ref : 415006  
POF Code: 200181/184113

The following statement is a full description of this invention, including the best method of performing it known to applicant(s):

## COSMETIC COMPOSITIONS HAVING KERATOLYTIC AND ANTI-ACNE ACTIVITY

### Technical Field

The invention is in the field of cosmetic compositions having keratolytic and anti-acne activity.

### Background of the Invention

*Acne vulgaris* is reported to be the most common skin disease, affecting approximately eighty percent of the teenage population, and in some cases persisting into the third and fourth decades of life. The pathology of acne is believed to first involve the formation of comedones, which are solid, horny masses of tightly packed keratinized cells which plug follicles. These comedone plugs are first white when formed (whiteheads), but through continued growth and deposition of melanin become blackheads. As the comedo enlarges through continued accumulation of keratinized cells, pressure builds up within the follicles and they eventually rupture, dumping the contents (consisting of horny material, sebum, and bacteria) into the skin. This provokes an inflammatory response: when the rupture is small pustules or pimples develop, and when the follicle completely ruptures cystic nodules result.

It is well known that *acne vulgaris* can be treated by application of agents which dry and peel the skin to remove keratinous plugs. Well known keratolytic agents are sulfur, resorcinol, benzoyl peroxide, salicylic acid, and hexachlorophene. Benzoyl peroxide is an antimicrobial agent which effectively suppresses the acne bacillus *Propionibacterium acnes*, an organism which has an important causal role in acne. In addition to being an effective keratolytic agent,

salicylic acid also interferes with the formation of blackheads, whiteheads, and the horny masses which clog follicles.

Salicylic acid, benzoyl peroxide, and resorcinol have been incorporated into various anti-acne preparations for years. However, due to the acidic nature of these ingredients, they often exert undesirable effects on the carrier formulation. Salicylic acid, for example, is not water soluble; it can only be solubilised in oils or alcohol. When salicylic acid is incorporated into these preparations at a pH of above 3, it converts to salicylate and causes stability problems in the formulation. Also, salicylic acid is light sensitive above a certain pH. Make-ups made with salicylic acid are known to fade on exposure to light and can be slightly irritating in sensitive skinned individuals who are prone to skin irritations. There is therefore a need for anti-acne preparations having improved stability and aesthetic properties.

#### Summary of the Invention

The invention is directed to a cosmetically acceptable composition with anti-keratolytic activity comprising:

0.01 to 25% by weight of a keratolytic compound complexed to a carrier molecule, 75-99.99% by weight of a diluent.

The invention is also directed to a method for treating acne vulgaris comprising:

- a) complexing a keratolytic compound to a carrier molecule,
- b) adding an effective amount of said complex of (a) to a cosmetically acceptable diluent.

Throughout the description and claims of this specification, the word "comprise" and variations of the word, such as "comprising" and "comprises", is not intended to exclude other additives, integers or process steps.

#### Detailed Description

It has most unexpectedly been discovered that if keratolytic compounds, particularly those

known to also have anti-acne activity are bound to a certain carrier molecules. the resulting complex will remain stable in cosmetic preparations. When the complex is applied to the skin in a cosmetic composition, the keratolytic compound becomes disassociated from the carrier molecule on the skin and is absorbed into the skin to provide the desired anti-acne effect. In the case of salicylic acid, the complexation of the salicylic acid in the cosmetic preparation is believed to prevent the conversion of salicylic acid to salicylate, and enhances the stability and aesthetics of the cosmetic preparation. The various ingredients of the cosmetically acceptable composition according to the invention are described in more detail below.

The term "keratolytic compound" means a chemical compound having keratolytic and/or anti-acne activity.

#### THE ANTI-ACNE ACTIVE

The keratolytic compounds which are suitable for use with the invention contain an acid group or tend to be acidic and are capable of binding with the free amino group of a protein or polymer. The binding may be ionic, covalent, or through Van Der Waals forces. Anti-acne ingredients capable of forming ionic bonds include salicylic acid and resorcinol. Benzoyl peroxide will bond to carrier molecules, or bind through Van der Waals forces.

#### THE CARRIER MOLECULE

A wide variety of carrier molecules are suitable, so long as the carrier molecule possesses at least one free amino group.

Animal protein or peptides such as collagen, placental proteins, serum proteins, amylase, casein, urease, keratin, silk, hydrolyzed animal protein, albumin, etc. are well known in the cosmetic art and are capable of ionic binding to the keratolytic compound. The preferred carrier

molecule comprises hydrolyzed animal protein, collagen, or keratin.

Vegetable or plant proteins or polyamino saccharides containing free amino groups are also suitable, such as soya, corn, sweet corn, lupin, wheat gluten, guar, oat, extensins, hydrolyzed vegetable proteins, and so on, as well as polymers of amino sugars such as chitosan. The preferred carrier molecule in this category comprises hydrolyzed vegetable protein, or extensins.

A wide variety of synthetic polymers have free amine groups are also suitable as the carrier molecule. Particularly desirable are branched polyamidoamines as set forth in U.S. patents 4,435,548, 4,737,550, 4,871,779, 4,857,599, 4,713,975, 4,694,064, 4,690,985, 4,631,337, 4,599,400, 4,587,329, 4,568,737, 4,558,120, and 4,507,466 which are hereby incorporated by reference. These patents disclose and claim dense star-type polymers with dendritic branches which have highly reactive substituent groups.

Other synthetic polymers such as polyamides, polyanilines, polyureas, polyurethanes, and contain at least one free amino group and would be suitable carrier molecules. Certain other polymers with free hydroxyl groups, such as polyvinyl alcohols, poly (2-HEMA) and poly (2-HPMA) will bind by Van der Waals forces.

#### COMPLEXATION OF THE KERATOLYTIC COMPOUND TO THE CARRIER MOLECULE

The keratolytic compound is attached to the carrier molecule employing a variety of chemical reactions depending on the carrier molecule and the anti-acne active used. The term "complex" refers to the keratolytic compound complexed or bound to the carrier molecule.

Salicylic acid and resorcinol have free acid groups which will ionically bond to the free amino groups of proteins or polymers. Binding of the salicylic acid to vegetable or animal

proteins is achieved by simply combining approximately equal parts of both ingredients in suitable vessel. The salicylic acid will react with the free amino groups on the carrier molecule to form a complex. Sometimes a slight degree of heat will hasten the reaction, or the addition of small amounts of acid such as hydrochloric acid. Salicylic acid may also be complexed to various carriers such as hydrolyzed vegetable proteins as described in French patent no. 2667072 which is hereby incorporated by reference. In particular, a concentrated solution of salicylic acid in alcohol is mixed with a concentrated solution of hydrolyzed vegetable protein in water. The resulting dispersion is mixed under shear or alternatively by ultrasonic agitation. Depending on the type of protein selected, the complex may precipitate upon forming or may be recovered by vacuum distillation or lyophilization by method known to those skilled in the art. The resulting powder effectively solubilizes the complexed salicylic acid which can be recovered and analyzed as salicylic acid by traditional wet chemistry. Alternatively, the salicylic acid can be rendered more water soluble by using a metal alkali salt such as sodium or potassium and complexing at a pH of 5.5 to 6.5. The powdered hydrolyzed protein is then added to a dispersion of the salicylate in a buffered water solution.

Salicylic acid can be complexed with the dendritic polymers disclosed herein. Dendritic polymers are constructed to vary in size and shape depending upon the initiator and the molecule used to grow the shell. Of particular interest are the starburst dendrimers of the polyamidoamine (PAMAM) type because the outer shell is covered with amino groups which will complex with salicylic acid. As in example one, the starting point can be either a water dispersion of dendrimer to which is added salicylic acid in a volatile solvent, or a solution of salicylate at pH 5.5 to 6.5 to which is added crystals of dendrimers. The size of the dendrimer



will allow multiple sites for complexation, but not so large that solubility in water is hindered. Dendrimers having 1-10 generations are ideal. Since the dendrimers can develop holes or irregularities, some salicylic acid may be sequestered within the shell as well as complexed to the surface. As with the protein, a high complexation ratio is desirable.

Salicylic acid will also bind to synthetic polymers which have free amino groups in a manner similar to binding to proteins. Such polymers include: polyamides  $-(R-CO-NH)_n-$ , polyanilines  $-(C_6H_5-NH)_n-$ , polyureas  $-(R-NHCONH)_n-$ , and polyurethanes  $-(CO-OR-OCO-NH-R'-NH)_n-$ , where the branched or terminal groups have free amino groups and the interior amine groups are also available.

Other polymers with free hydroxy groups will bind to salicylic acid by Van der Waals forces. Such polymers are polyvinyl vinyl alcohols  $-(CH_2CHOH)-$ , poly(2-HEMA),

$-(CH_2-C(CH_3)(COOCH_2CH(OH)-))_n-$ , and poly(2-HPMA),

$-(CH_2-C(CH_3)(COOCH_2CH_2OH)-)_n$  and  $-(CH_2-C(CH_3)(COOCH_2CH(OH)CH_3)_n-$ . Such bonds are weaker, but may be enhanced by shared electrons across the aromatic ring of salicylic acid.

Benzoyl peroxide will only form Van der Waals bonds with proteins or polymers. The complexation of benzoyl peroxide to proteins is achieved by sharing electrons across the peroxide moiety and the amido moiety in the polymer.

It is generally preferred that the complex be comprised of 40-50% by weight of anti-acne active and 50-60% by weight of carrier molecule. Ratios may vary depending on the effect desired. For example, in some cases it may be desired to have small levels of the anti-acne active deposited on the skin, in which case more appropriate ratios might range from 10-40% anti-acne active/60-90% carrier molecule, or vice versa.

It may be desired to encapsulate the complex to provide additional properties such as time release. Standard encapsulation methods are suitable, such as the methods disclosed in U.S. patent no. 5,194,262 which is hereby incorporated by reference.

### THE DILUENT

The term "diluent" generally refers to a composition applied externally to the skin or hair of the human body for the purpose of cleansing, beautifying, conditioning or protecting the body surface. A wide variety of diluents is suitable including but not limited to water-in-oil or oil-in-water emulsions in cream or lotion form, sunscreens, toners, astringents, facial make-ups, pressed or loose powder, skin cleansing compositions, and so on. In some cases it may be desired to apply the complex to the scalp to achieve keratolytic effects, so suitable diluents can also include shampoos and conditioners. In general, the cosmetically acceptable compositions of the invention contain about 0.1-30% of the complex and about 70-99.9% diluent. Preferably the compositions comprise about 0.1-10% complex and 90-99.9% diluent.

The complex may be incorporated into creams. Creams generally contain about 10-90% water and 10-90% oil. The oil may be low or high viscosity surface oils, volatile silicones, nonvolatile silicones, or amine functional silicones. Creams may also contain humectants, emollients, surfactants, emulsifiers, preservatives and fragrances. About 5-10% humectant, 5-20% emollient, and about 0.5-10% surfactant or emulsifier is suggested.

The diluent may be a lotion. Lotions are generally comprised of 20-80% oil and 10-80% water in an emulsion form. In addition, lotions may contain humectants, emollients, surfactants, fragrances, preservatives and so forth. About 5-10% humectant, about 5-20% emollient, and about 0.5-10% surfactant are suggested.

The diluent may be a make-up. Make-ups generally comprise about 5-70% oil, 10-95% water, and about 5-40% pigment. In addition, the makeup may contain surfactants, silicones as part of the oil phase, humectants, emollients, preservatives, fragrances, etc. Generally 0.1-10% surfactant, 0.1-50% silicone, 0.1-20% humectant, 0.1-30% emollient, and 0.1-5% preservative is suggested. In the preferred embodiment of the invention the diluent is a make-up comprising 0.01-50% silicone, 30-60% water, 0.01-40% pigment, and 5-40% oil. The preferred composition may also comprise 0.1-20% humectant, 0.1-10% surfactant, and 0.1-5% preservative.

The make-up of the invention provides improved properties over the anti-acne make-ups currently available in that it does not change color or fade. Normally anti-acne actives, salicylic acid in particular, react with the iron oxide pigments commonly used in make-up. However, because the anti-acne active is bound to a carrier molecule, such reaction does not occur in the make-up composition of the invention.

The diluent may also be a blush, face powder, or other anhydrous makeup. Generally blushes contain about 5-75% pigment, 1-50% oil, and 1-20% wax. They may additionally contain one or more of 10-60% water, 0.5-30% surfactant, 1-10% humectants, 0.1-5% preservative, and 0.1-20% silicone. Anhydrous makeups and concealers generally comprise one or more of 0.1-10% surfactant, 0.1-50% silicone, 0-20% humectant, 0.1-30% emollient, 0.1-50% pigment and 0.1-5% preservative. Face powders comprise 5-75% powder, 0.1-20% wax, and 0.01-20% pigments. They may also contain one or more of 10-60% water, 0.5-30% surfactant, 1-10% humectants, 0.1-5% preservative, and 0.1-20% silicone.

The diluent may be a shampoo when it is desired to apply the anti-acne active (which also

has keratolytic activity) onto the scalp. Suitable shampoo compositions contain 1-40% of a cleansing surfactant and 10-90% water. Preferably the surfactants are anionic or amphoteric. The shampoo may also contain any one of ingredients such as surfactants, colorants, preservatives, fragrance, emulsifiers, viscosity adjusters, and conditioning agents. If present, suitable ranges are 0.01-30% surfactant, 0.001-5% colorant, 0.001-5% preservative, 0.01-15% emulsifiers, 0.01-10% viscosity adjusters, and 0.1-20% conditioning agents.

The diluent may also be a hair conditioner. Suitable hair conditioning formulations include 10-95% water, 0.5-30% conditioning ingredients such as quaternary ammonium compounds or amphoteric polymers, proteins, etc., and 1-40% surfactants. Hair conditioners may also contain volatile or nonvolatile silicones; an amount of about 0.5-15% is suggested.

The diluent may be a toner which generally comprises about 0-85% alcohol, 0.01-5% surfactant, and 0.1-5% humectants, 0.1-85% water.

The diluent may also be pharmaceutical type vehicles such as ointments, gels or solutions. Suitable ointments are hydrophilic ointments (USP) or petrolatum. Solutions are made by mixing the anti-acne active/carrier molecule complex in deionized water. Gels generally comprised about 1-90% water and about 1-90% of a suitable polymer such as polypropylene, etc.

Suitable emollients include glyceryl stearate, cetyl alcohol, stearyl alcohol, isopropyl stearate, stearyl stearate, isopropyl stearate, stearic acid, isobutyl palmitate, isocetyl stearate, oleyl alcohol, sebacates, myristates, palmitates, squalenes, glyceryl monooleate, oleic acids, lanolin, acetylated lanolin alcohols, petrolatum, mineral oils, palmitic acids, isostearyl neopentanoate, etc., as well as those set forth on pages 79-81 of the C.T.F.A. Cosmetic

Ingredient Handbook, First Edition, 1988, which is hereby incorporated by reference.

Suitable humectants include glycerin, butylene glycol, propylene glycol, glucose, fructose, glucuronic acid, glucamine, glutamic acid, glycereth-7, glycereth-12, glycereth-26, histidine, honey, lactose, mannitol, methyl gluceth, sodium PCA, PEG-10 propylene glycol, urea, xylitol, TEA-lactate, TEA-PCA, sucrose, sorbitol, PCA, sodium lactate, or mixtures thereof, as well as those set forth on page 75 of the C.T.F.A. Cosmetic Ingredient Handbook, First Edition, 1988, which is hereby incorporated by reference.

A variety of surfactants may be used in the diluent including amphoteric, anionic, cationic or nonionic surfactants. Suitable amphoteric surfactants include imidazolines, betaines, and amino acid salts. Suitable anionic surfactants include fatty acid soaps, salts of higher alkyl sulfates, n-acyl sarcosinates, salts of phosphates, sulfosuccinates salts, alkyl benzene sulfonates, salts of N-acyl glutamate, polyoxyethylene alkyl ether carboxylic acids, and so on. Cationic surfactants include alkyl trimethyl ammonium salts, alkyl pyridinium salts, alkyl quaternary ammonium salts, polyamine fatty acid derivatives, etc. Suitable anionic and amphoteric surfactants also include those designated as "cleansing agents" as set forth on pages 87-90 of the C.T.F.A. Cosmetic Ingredient Handbook, First Edition, 1988, which is hereby incorporated by reference. Nonionic surfactants include lipophilics such as sorbitan fatty acid esters, glycerol fatty acids, propylene glycol fatty acid esters; hydrophilics such as polyoxyethylene sorbitan fatty acid esters, polyoxyethylene glycerol fatty acid esters, polyoxyethylene fatty acid esters, polyoxyethylene alkyl ethers, pluronics, polyoxyethylene alkyl phenyl ethers, polyoxyethylene propylene glycol fatty acid esters, and so on. Examples of nonionic surfactants include those set forth in pages 90-94 of the C.T.F.A. Cosmetic Ingredient Handbook, First Edition, 1988.

which is hereby incorporated by reference. Suitable cationic surfactants are set forth on page 97 of the C.T.F.A. Cosmetic Ingredient Handbook, First Edition, 1988, which is hereby incorporated by reference.

Suitable pigments include organic and inorganic pigments such as talc, mica, titanium dioxide, titanated mica, iron oxides, ultramarines, chromium oxides, carmine, D&C and FD&C colors and lakes, ferric and ferrous oxides, and so on, as set forth on pages 33 and 63 of the C.T.F.A. Cosmetic Ingredient Handbook, First Edition, 1988, which is hereby incorporated by reference.

Suitable preservatives include the ureas such as imidazolidinyl urea, diazolidinyl urea, the parabens, quaternium 15, benzyl alcohol, phenoxyethanol and so on.

Suitable waxes include beeswax, cetyl esters, carnauba, ceresin, microcrystalline, lanolin, paraffin, ozokerite, lanolin alcohol, acetylated lanolin, candelilla, cetyl alcohol, cocoa butter, petrolatum, hydrogenated castor oil, spermacetic, bran wax, capok wax, bayberry, hydrogenated jojoba oil, hydrogenated jojoba wax, hydrogenated rice bran wax, japan wax, jojoba butter, jojoba oil, mink, montan acid, montan, ouricury, shellac, etc.

Suitable silicones include cyclomethicone, dimethicone, stearyl dimethicone, phenyl trimethicone, dimethiconol, dimethicone copolyols, etc.

In the preferred embodiment of the invention the anti-acne active/carrier molecule complex comprises 40-50% by weight plant protein (hydrolyzed vegetable protein) and 45-55% salicylic acid. The preferred diluent is a make-up or skin care product.

#### EXAMPLE 1

A concentrated solution of hydrolyzed vegetable protein in water is mixed with a 50%

1 salicylic acid solution in ethanol. The resulting dispersion is mixed under shear. The mixture  
2 is allowed to stand for approximately 24 hours. Lyophilization is performed to yield a powdered  
3 material which comprises salicylic acid complexed to the hydrolyzed vegetable protein.

#### 4 EXAMPLE 2

5 A water dispersion of about 50 wt% polyamidoamine methacrylate crystals in water is  
6 prepared. A solution of 50% salicylic acid in ethanol is slowly added to the crystals with  
7 stirring for a half hour. The mixture is vacuum distilled to yield crystals having salicylic acid  
8 complexed thereto.

#### 9 EXAMPLE 3

10 A concentrated dispersion of polyacrylamide in water is mixed with a 50% solution of  
11 salicylic acid in ethanol with high shear mixing. After 24 hours the resulting dispersion is  
12 lyophilized to yield crystals having salicylic acid complexed thereto.

#### 13 EXAMPLE 4

14 A 50% solution of benzoyl peroxide in ethanol is mixed with a 25% solution of  
15 hydrolyzed vegetable protein. The mixture is allowed to stand for 24 hours. The mixture is  
16 then lyophilized to obtain a powder. The powder comprises hydrolyzed vegetable protein having  
17 benzoyl peroxide complexed thereto.

#### 18 EXAMPLE 5

19 The salicylic complex of Example 1 was used to prepare a make-up composition as  
20 follows:

	<u>w/w %</u>
21 Salicylic acid/hydrolyzed veg. protein complex	1.00
22 Trisodium EDTA	0.15

Benzoic acid	0.20
1.3-butylene glycol	5.00
Sodium polymethacrylate	1.00
Sorbitan sesquioleate	0.50
Simethicone	0.15
Glycerin	5.00
Magnesium aluminum silicate	1.25
Methyl paraben	0.30
Ethyl paraben	0.10
Polyethylene	2.00
Nylon 12	3.00
Rutile titanium dioxide	5.00
Black iron oxide/talc	0.53
Red iron oxide/talc	0.92
Yellow iron oxide	0.69
Talc	3.44
Xanthan gum	0.35
Cyclomethicone	15.00
Diisononyl linoleate	3.50
Polysorbate 20	1.00
Water	0.70
Imidazolidinyl urea	0.30

Water was heated to 60-65° C. Salicylic acid/hydrolyzed vegetable protein complex.

trisodium EDTA, benzoic acid, 1.3-butylene glycol, sodium polymethacrylate, sorbitan sesquioleate, simethicone, glycerin, magnesium aluminum silicate, methyl paraben, ethyl

paraben, polyethylene, nylon 12, the oxides, talc and xanthan gum were mixed in a colloid mill until all ingredients were dispersed. The mixture was then heated in a steam bath to 68-70° C.

using a sweep mixer. Next combined were the oil phase ingredients: cyclomethicone, diisopropyl linoleate and polysorbate 20. The mixture was heated in a steam bath to 68-70° C.

When the water and oil phases were at the same temperature, they were mixed with sweep action to form the emulsion. Sweep mixing was continued at the maintenance temperature for 15-20 minutes. The mixture was then removed from the bath and allowed to cool while maintaining mixing. The urea was added when the batch temperature reach 40-45° C.



### EXAMPLE 6

An oil in water moisturizing lotion is made as follows:

	<u>w/w %</u>
Glyceryl stearate	3.0
PPG-10 lanolin ether	0.5
Mineral oil	6.3
Lanolin alcohol	0.7
Oleic acid	2.7
Isocetyl stearate	10.00
Triethanolamine	1.3
Carbomer 941	0.1
Glycerin	4.0
Preservative	0.4
Salicylic acid/hydrolyzed vegetable protein complex	5.00
QS water	100.00

The lotion was made by mixing into about 30 grams of water the remaining ingredients.

The composition was emulsified and water added to 100 grams.

### EXAMPLE 7

An oil-in-water moisturizing cream is made as follows:

	<u>w/w %</u>
Glyceryl stearate	5.0
Cetyl alcohol	2.0
Stearyl alcohol	2.0
Isopropyl stearate	4.0
Mineral oil	12.0
Polysorbate 60	1.0
Glycerin	8.0
Xanthan gum	0.25
Preservative	0.60
Salicylic acid/hydrolyzed vegetable protein complex	5.00
Water QS	100.00

The ingredients were combined and mixed to emulsify.

### EXAMPLE 8

An anhydrous makeup with salicylic acid was made as follows:

#### w/w%

Stearoyl dimethicone	12.00
Phenyl trimethicone	16.00
Octyldodecanol	12.00
Dimethicone	4.00
BHA	0.10
Phenoxyethanol	0.70
Titanium dioxide	15.00
Black iron oxide/talc	0.26
Red iron oxide/talc	2.00
Yellow iron oxide/talc	5.00
Talc	6.94
Lecithin treated mica	6.00
Hydrogenated coco glycerides	10.00
Ceresin wax	1.00
Tribehenin	8.00
Salicylic acid/hydrolyzed vegetable protein protein complex	1.00

All ingredients except the complexed salicylic acid/protein was mixed in a steam bath until waxes were molten. The entire batch was roller milled until pigments were dispersed. The mixture was then returned to the steam bath and the salicylic acid complex was added. The batch was prop mixed until cooled to room temperature.

### EXAMPLE 9

An anhydrous concealer stick was made as follows:

#### w/w%

Ceresin wax	15.00
Carnauba	2.00
Wax blend	4.00
Microcrystalline wax	2.50
Ester blend	30.00
Prepolymer 2	10.00

1	Octyldodecanol	13.00
2	Sorbitan sesquioleate	1.00
3	Octyldodecyl stearoyl stearate	2.00
4	Bismuth oxychloride	2.00
5	Polymethylmethacrylate	3.00
6	Talc	5.70
7	Lecithin treated black I.O.	1.00
8	Lecithin treated red I.O.	2.00
9	Lecithin treated yellow I.O.	5.00
0	Phenoxyethanol	0.70
1	BHA	0.10
2	Salicylic acid/hydrolyzed vegetable protein	
3	complex	1.00

All ingredients except the salicylic acid/protein complex were mixed in a steam bath until waxes were molten. The entire batch was roller milled until pigments were dispersed. The batch was returned to the steam bath and the salicylic acid complex was added. The batch was prop mixed until it cooled to room temperature.

#### EXAMPLE 10

A shampoo composition was made as follows:

w/w %

3	Ammonium lauryl sulfate	10.00
4	Cocamide diethanolamine	4.00
5	Cocamidopropyl betaine	4.00
6	Ammonium chloride	0.80
7	Citric acid	0.10
8	Salicylic acid/hydrolyzed vegetable protein complex	5.00
9	Water QS	100.00

#### EXAMPLE 11

A creme rinse hair conditioner was made as follows:

w/w %

Stearalkonium chloride	2.0
Cetyl alcohol	1.0
Stearyl alcohol	0.5
Ceteareth 20	2.0
Xanthan gum	0.5
Citric acid	0.3
Dimethicone	0.2
Salicylic acid/hydrolyzed vegetable protein complex	5.00
Water QS	100.00

### EXAMPLE 12

A toner composition was made as follows:

	<u>w/w %</u>
Polysorbate 20	1.0
Ethyl alcohol	50.00
Perfume	8.00
Salicylic acid/hydrolyzed vegetable protein complex	10.00
Water QS	100.00

### EXAMPLE 13

A cleansing cream was made as follows:

	<u>w/w %</u>
Mineral oil	20.00
Beeswax	2.00
Polysorbate 40	8.00
PEG 20 sorbitan beeswax	2.00
Stearic acid	10.00
Petrolatum	4.00
Sorbitol	5.00
Perfume	1.00
Preservative	0.50
Salicylic acid/hydrolyzed veg. protein complex	10.00
Water QS	100.00

The claims defining the invention are as follows:

1. A cosmetically acceptable composition with keratolytic activity comprising:  
0.01 to 25% by weight of a keratolytic compound complexed to a carrier  
5 molecule,  
75-99.99% by weight of a diluent.
2. A composition according to claim 1 wherein the keratolytic compound is  
resorcinol, benzoyl peroxide, salicylic acid, or mixtures thereof.
3. A composition according to claim 1 or 2 wherein the carrier molecule is  
10 hydrolysed vegetable protein, hydrolysed animal protein, a branched polyamidoamine,  
a polyamide, polyaniline, polyurea, polyurethane, polyvinyl alcohol derivative, or  
mixtures thereof.
4. A composition according to claim 3 wherein the carrier molecule is complexed to  
the keratolytic compound by ionic, covalent, or Van der Waals bonding.
- 15 5. A composition according to any one of the preceding claims wherein the diluent  
is a cream, lotion, make-up, blush, skin cleanser, sunscreen, toner, astringent, or  
powder.
6. A composition according to claim 4 wherein the complex comprises 10-40% by  
weight of the complex of keratolytic compound and 60-90% by weight of the complex of  
20 carrier molecule.
7. A composition according to any one of the preceding claims comprising 0.01-  
20% by weight of the total composition of the keratolytic ingredient/carrier molecule  
complex and 80-99.9% by weight of the total composition of diluent.
8. A composition according to any one of the preceding claims wherein the diluent  
25 is a make-up containing 5-70% oil, 10-95% water, and 5-40% pigment.
9. A composition according to claim 8 wherein the make-up comprises 0.01-50%  
silicone, 30-60% water, 0.01-40% pigment and 5-40% oil.
10. A composition according to claim 9 wherein the make-up additionally comprises  
0.1-20% humectant, 0.1-10% surfactant, and 0.1-5% preservative.
- 30 11. A method for treating acne vulgaris comprising:  
(a) complexing a keratolytic compound to a carrier molecule,

(b) adding an effective amount of said complex of (a) to a cosmetically acceptable diluent.

(c) applying the composition of (b) to a subject's face at least once per day.

12. A method according to claim 11 wherein the keratolytic compound is an salicylic acid.

13. A method according to claim 11 or 12 wherein the diluent is a make-up.

14. A method according to any one of claims 1 to 13 wherein the carrier molecule is hydrolysed vegetable protein.

15. A method according to claims 12 to 14 wherein the salicylic acid is ionically bound to hydrolysed vegetable protein.

16. A method according to claim 13 wherein the make-up comprises 5-70% oil, 10-95% water, and 5-40% pigment.

17. The method according to claim 16 wherein the make-up comprises 0.01-50% silicone, 30-60% water, 0.01-40% pigment and 5-40% oil.

18. A facial make-up composition having anti-keratolytic activity comprising:  
a keratolytic compound complexed to a carrier molecule comprising, by weight of the total composition:

0.01-10% of salicylic acid ionically bound to hydrolysed vegetable protein, and  
a diluent which comprises, by weight of the total composition:

0.01-50% silicone

0.01-40% pigment, and

5-40% oil,

wherein when the make-up composition is applied to the face the ionic bond between the salicylic acid and the hydrolysed vegetable protein is ruptured and the free salicylic acid is absorbed onto the skin.

19. A composition according to claim 18 further comprising 0.1-10% surfactant, 0.1-20% numectant, 0.1-30% emollient, or mixtures thereof.

20. A composition according to claim 17 wherein the silicone is a mixture of volatile and nonvolatile silicone.

21. A composition, according to claim 1, substantially as hereinbefore described with reference to any one of the examples.

22. A method, according to claim 11, substantially as hereinbefore described with  
referenc to any one of the examples.

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### ABSTRACT OF DISCLOSURE

A cosmetically acceptable composition with anti-acne or keratolytic activity comprising:  
0.01 to 25% by weight of a keratolytic compound complexed to a carrier molecule,  
75-99.95% by weight of a diluent.

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